

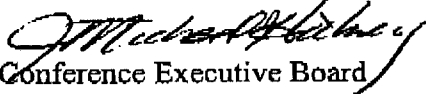
**Interstate Shellfish Sanitation Conference**

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April 16, 1999

To: Dockets Management Branch (HFA - 305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

From: J. Michael Hickey, Chairman 
Interstate Shellfish Sanitation Conference Executive Board

RE: Federal Register Notice
Performance Standards for *Vibrio vulnificus*, Request for comments
Docket No. 98P - 0504

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the U.S. Food & Drug Administration's (FDA) *Federal Register* notice requesting information and views on the Center for Science in the Public Interest (CSPI) petition and on several specific questions relating to the petition.

The illnesses and deaths associated with the consumption of raw molluscan shellfish containing *Vibrio vulnificus* are of significant concern to the Interstate Shellfish Sanitation Conference. The Conference acknowledges the health implications of this concern and is continuing to work with the FDA on several important cooperative efforts which will provide needed information in addressing this difficult and unique concern. These cooperative efforts have not been completed, and it is the opinion of the ISSC Executive Board that any decision regarding establishment of a performance standard for *Vv* would be premature at this time. The ISSC Executive Board strongly urges the FDA to delay any action on the petition until the information from the ISSC/FDA's cooperative efforts is available. Should FDA be unable to delay action, the ISSC Executive Board recommends denial of the petition. The joint ISSC/FDA efforts are listed below.

1. The ISSC is finalizing, with FDA input, the scope of a study to determine the economic impact of establishing a performance standard of "non-detectable" for *Vibrio vulnificus*. The decision to conduct this study was the result of recommendation from Philip Spiller Director, FDA Office of Seafood. Mr. Spiller, in opening remarks to the 1998 ISSC membership, urged the Conference to conduct an economic assessment and consider the economic impact in developing strategies for addressing health issues associated with *Vv* in shellfish. The economic study will be conducted by Research Triangle Institute (RTI) of Research Triangle Park, North Carolina. RTI has conducted economic studies on several food commodities for the FDA and the U. S. Department of Agriculture in several food areas.

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2. In 1998 Issue 98-106 was submitted to the ISSC which included recommendations similar to those included in the CSPI petition. This issue proposed a *Vv* control plan which included a performance standard for *Vv* in states which have been confirmed as the original source of shellfish associated with the two or more *Vv* illnesses for the previous two years. The ISSC voting delegates referred Issue 98-106 to committee for development of recommendations. The FDA, in its January 22, 1999, response to the 1998 Summary of Actions, requested the committee consider nine (9) questions related to the establishment of a performance standard. The committee will provide recommendations to the ISSC during the July, 1999 annual meeting. These recommendations should be considered by the FDA prior to any action on the CSPI petition.
3. The ISSC is working collectively with the FDA and nine states in a *Vibrio* Retail Study to determine levels of *V. vulnificus* and *V. parahaemolyticus* found in shellstock in retail establishments. The laboratory analysis and data collection are being coordinated by the FDA laboratory in Dauphin Island, Alabama. The FDA provided preliminary data to the ISSC Executive Board in March, 1999. The results of this study will be helpful in addressing vibrios. In particular, identification of total levels, regional differences in pathogenic strains, and levels of pathogenic strains will be helpful to the ISSC in its deliberations concerning a performance standard for *Vv*.

The FDA has agreed in a Memorandum of Understanding to recognize the ISSC as the primary voluntary national organization of State shellfish regulatory officials to provide guidance and counsel on matters for the sanitary control of shellfish. The ISSC will review the appropriateness of a performance standard for *Vv* based on the information outlined in 1, 2 & 3 above and will make recommendations to the FDA in the Summary of Actions as outlined in the ISSC Constitution By Laws and Procedures. To facilitate ISSC discussions on Issue 98-106, the FDA is requested to submit any information or petition comments the agency deems relevant to the development of a *Vv* performance standard. Delaying action on the petition until the ISSC reviews the appropriate information and makes its recommendations to the FDA. This action will assure conference involvement and provides opportunity for input by the participating partners of the National Shellfish Sanitation Program.



Interstate Shellfish Sanitation Conference

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Pages: 3

Response to:

Federal Register Notice

Performance Standards for *Vibrio vulnificus*, Request for comments

Docket No. 98P -0504

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